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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,316	04/21/2004	Joel R. Studin	SDF 04-14	5671

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1618	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,316	STUDIN, JOEL R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 30-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 30-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. 1.114 filed 11/07/07 and the Amendment and Applicant's Arguments/Remarks filed 10/11/07 is acknowledged.

Applicant has overcome the following rejection(s): (1) The 35 U.S.C. §112, first paragraph rejection of claims 1-16 and 30-32 based on the term "prevent" has been withdrawn, by virtue of the amendment which deletes the term "prevent" from claims 1 and 30. (2) The 35 U.S.C. §103(a) rejection of claims 1-16 and 30-32 as being unpatentable over Zhang *et al.* (USPN 6,528,086) and Tipton *et al.* (USPN 5,632,727) has been withdrawn, by virtue of the submission of the Rule 1.131 Declaration.

Claims 1-16 and 30-32 are pending in this action. Claims 1 and 30 have been amended. Claims 17-29 and 33-54 have previously been cancelled. Claims 1-16 and 30-32 are rejected.

* * * * *

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/07 has been entered.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519), (hereafter "Youssefyeh") in view of Lee (U.S. Pat. No. 5,552,162).

Youssefyeh *et al.* ('519) teach a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier (see Abstract); (column 1, lines 10-18). Youssefyeh teach that the method of treatment for the relief of inflammation and/or pain associated with inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder

of safflower seed or its extract sufficient to induce alleviation of signs, symptoms or causes of inflammation or pain in a pharmaceutically acceptable carrier (col. 11, line 49 – col. 12, line 58); (col. 13, line 53 – col. 14, line 7); (col. 22, line 64 – col. 24, line 13). Youssefyeh teach that for topical administration, the compositions may contain certain pharmaceutical and therapeutical agents either singularly or in combination of which suitable pharmaceutical/therapeutical agents disclosed include anti-inflammatory corticosteroids, such as progesterone, hydrocortisone, prednisone, triamcinolone and dexamethasone. Additional agents disclosed include anti-inflammatory analgesics, local anesthetics, antibacterial agents and antiseptic agents. It is also taught that the topical compositions can be in the forms of ointments, creams, lotions, solutions, dressings and patches and slow-release preparations and film-forming preparations (col. 14, lines 19-40); (col. 15, lines 29-60).

Topical formulations can be prepared by combining the finely divided safflower seed or its extract with conventional pharmaceutical carriers or diluents used in topical dry, liquid and cream formulations. Ointments and creams may be formulated with an aqueous or oil base with the addition of suitable thickening or gelling agents (col. 15, lines 29-60). Ointments, pastes, creams and gels may contain excipients such as cellulose derivatives and silicones (col. 15, lines 43-46).

A preferred form of topical delivery is film-forming materials loaded with finely divided powder of safflower seed or its extract. Suitable film-forming materials taught include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other synthetic polymers (col. 15, line 61 – col. 17, line 19); and claim 12. Upon application, the formulation is deposited on the desired area and allowed to form a film, which by the presence of

water in the skin environment, will allow slow delivery of the active agent onto the area being treated (col. 17, lines 20-23).

Applicants claim, "hardening the carrier into a tangible membrane" in claim 1. The instant claims differ from the prior art in that Youssefyeh do not specifically teach a "membrane" as instantly claimed. However, they nonetheless teach that the topical formulation is deposited onto the desired area and allowed to *form a film*, which will allow for slow release of active agent onto the treatment area. Thus, the "film" taught by Youssefyeh is functionally equivalent to the "membrane" claimed by Applicant.

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches methods for treating inflammatory dermal conditions, both acute and chronic and teaches that suitable topical applications include film-forming preparations (see col. 13, line 53 – col. 14, line 40). The method comprises topical administration of safflower oil in combination with a corticosteroid and a pharmaceutically acceptable carrier, whereby upon application, the formulation is deposited on the skin to form a film for the release of active agent onto the treatment area. The methods of treatment and conditions to be treated as taught by Youssefyeh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof.

Youssefyeh do not teach vitamin E, collagenase and treating a hypertrophic scar.

Lee ('162) teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or

thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

Lee teaches that the collagenase is provided in the composition in order for the effective breakdown and degradation of collagen (col. 7, lines 44-62). Vitamins such as vitamin E are included in the composition (col. 11, lines 35-52).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefyeh. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars, including hypertrophic scars, which comprises applying a thermal material or hydrogel containing suitable ingredients such as vitamin E and collagenase, used for the degradation of collagen. The expected result would an enhanced method for treating dermatological disorders and conditions.

* * * * *

Claims 1-16 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162).

Mantelle ('070) teaches flexible, finite, bioadhesive compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier

and methods of administering the pharmaceutical agents (see Abstract); (col. 1, lines 18-34); (col. 4, line 24 – col. 5, line 62).

The composition when administered topically, for example to an area of the skin, delivers a pharmaceutical agent or a combination of agents to produce a local or systemic effect over a prolonged period of time (col. 5, line 65 – col. 6, line 3).

Suitable active agents disclosed for use in the invention include anti-inflammatory drugs, corticosteroids and the like (col. 23, line 32 – col. 41, line 39); claim 4; Examples 30-32.

Suitable adhesive carriers are disclosed at column 12, lines 55-65 and include cellulose derivatives, silicones.

Mantelle teaches the inclusion of enzymes, such as the proteolytic enzyme – collagenase (col. 38, line 4). Mantelle also teaches vitamins, such as vitamin E (col. 41, lines 35-36).

While the prior art does not explicitly teach treatment of "healed wounds", the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for the effective treatment of pain. The method comprises applying a therapeutically effective amount of a pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin.

Mantelle does not teach treating a hypertrophic scar.

Lee ('162) teach a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain

a therapeutically effective amount of medicament (see Abstract); (column 1, lines 41-54); (col. 6, lines 17-49); (col. 11, lines 19-34).

The compositions taught by Lee are particularly effective for improving the size and appearance of hypertrophic scars (see claim 7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle. One would do so with a reasonable expectation of success because Lee explicitly teaches methods for improving the size and appearance of scars whereby the compositions are especially beneficial for improving hypertrophic scar formation. The expected result would an improved method for treating dermal skin conditions.

* * * * *

Response to Arguments

Applicant's arguments, see Response, filed 10/11/07, with respect to the rejection(s) of claim(s) 1-16 and 30-32 under 35 U.S.C. §112, 1st paragraph and the rejection of claims 1-16 and 30-32 under 35 U.S.C. §103(a) over Zhang et al. (USPN 6,528,086) and Tipton et al. (USPN5,632,727) have been fully considered and are persuasive. Therefore, the rejections have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the Youssefyeh et al. ('519), Mantelle ('070) and Tipton et al. ('727) references.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley, can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1618

HUMERA N SHEIKH
PRIMARY EXAMINER

February 04, 2008

hns